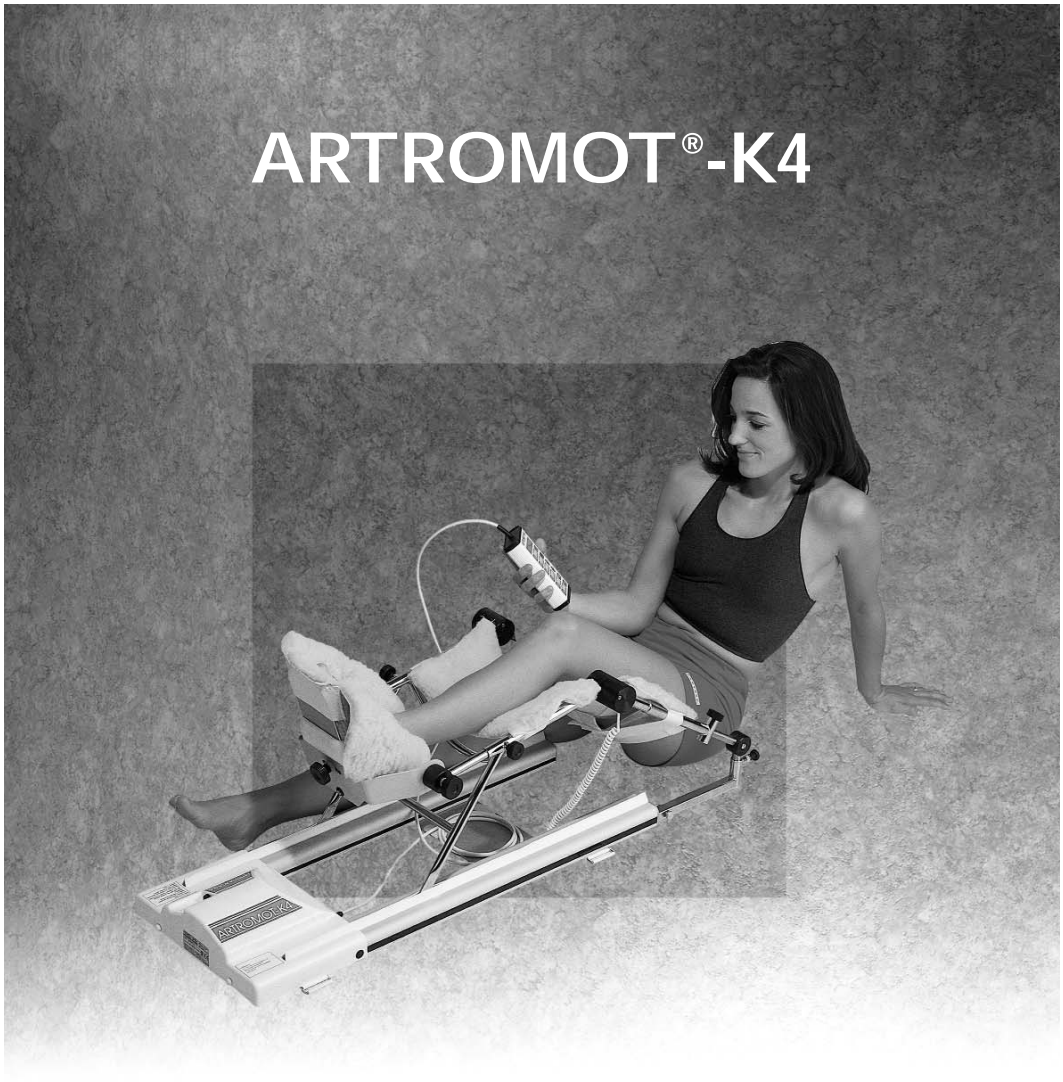
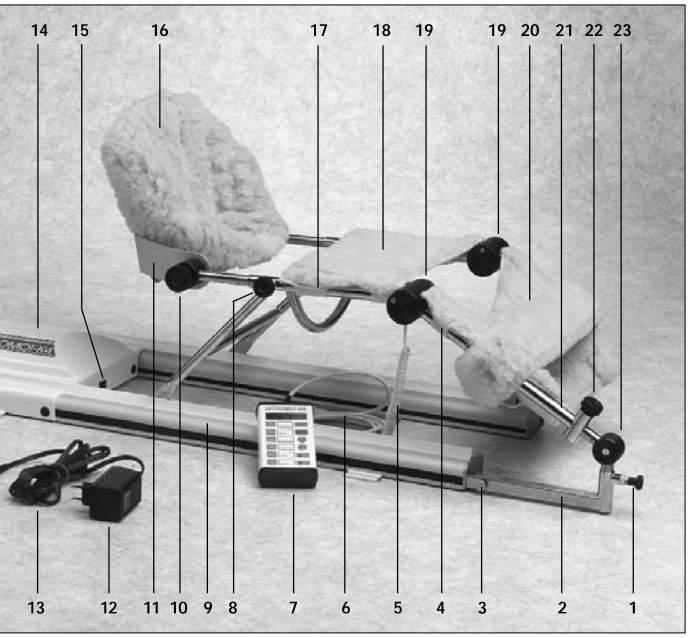
ARTROMOT®-K4

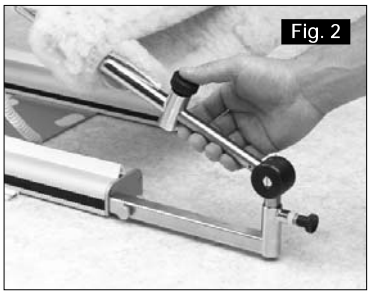


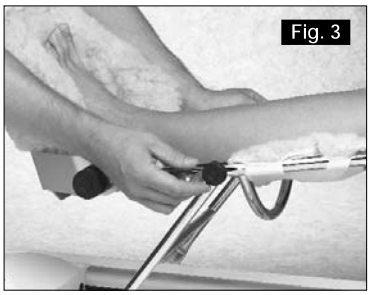
Operation Manual

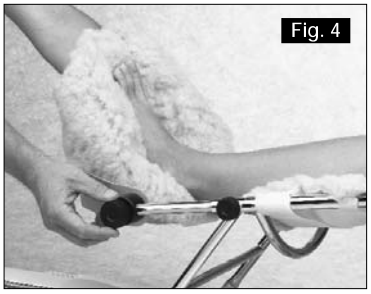
e description

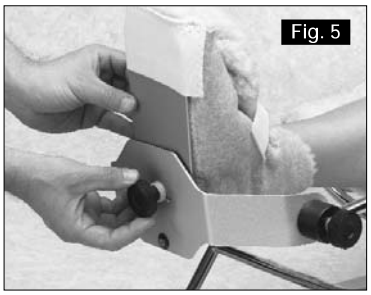


Figures









nts

1. How to use ARTROMOT®-K4

1.1 Application

The **ARTROMOT®-K4** is a motor-operated motion device used for **C**ontinuous **P**assive **M**otion (**CPM**) of the knee and hip joints.

Suitable for use in hospitals, clinics, general practices and rental services, it is an important supplement to medical and therapeutic treatment.

1.2 Objectives of therapy

CPM therapy with **ARTROMOT®-K4** is mainly used in the avoidence of immobilisation injuries, the early reestablishment of painless movement of joints and the promotion of faster healing with a positive functional result.

Other objectives of therapy include:

- the improvement of joint meatbolism
- the prevention of joint stiffness
- the promotion of the healing of cartilage areas and damaged ligaments
- the speeding up of haematoma resorbtion
- the improvement of lymph and blood circulation
- the prevention of thrombosis and embolism

1.3 Indications

The **ARTROMOT®-K4** CPM d
is indicated in the treatment o
injuries, postoperative states a
diseases of the knee and hip j
For example:

- joint distorsions and contusi
- arthrotomy and arthroscopy
  procedures in combination v
  synovectomy, arthrolysis or
  intra articular measures
- mobilsations of joints in narc
- operative treatments on frac
  pseudarthrosis and inversion
  tions
- criciate ligament replacemer
  (ACL/PCL)
- endoprothetic implants

⚠ PRECAUTION

**The ARTROMOT®-K4 shou
be used with:**

- **acute inflammatory proc
  in the joint area, if not e
  prescribed by the docto**
- **spastic paralysis**
- **unstable osteosynthesis**

**Movement should not cau
pain.**

scription of the ARTROMOT®-K4

OMOT®-K4 CPM device
ension and flexion of the
n the range of -10-0-125
d of the hip joint in the range
degrees.

OMOT®-K4 features a
programming unit that can
program and store any
values.

ion of the functioning
s

l out page 2

for heigth adjustment of hip
oint

ube

e tubes for square tube

kit strapes

cord

ler cable

eld programming unit

or length adjustment
r leg

or angle adjustment of foot
ion

or rotation footplate

adapter

f power adapter

for power adapter

15 Main switch

16 Footplate with patient kit

17 Lower leg support

18 Lower leg patient kit

19 Knee pivot point

20 Thigh patient kit

21 Thigh support

22 Knob for femur length adjustment

23 Hip axis pivot point

Explanation of symbols

~	Alternating current
	Protective system Type B
○	Power off
|	Power on
◯	Device off
⊙	Device on

3. Safety instructions

⚠ PRECAUTION!
these instructions must be read before start-up!

- The **ARTROMOT®-K4** may only be operated by **authorised persons**.
- Make sure that the patient is supported in an anatomically correct way. Check the following settings/positioning:
  1. Femur length
  2. Knee joint axis
  3. Hip joint axis
  4. Calf length and leg rotation setting
  5. Patient kits
- In case of patients who are **adipose, particular large or very small**, you should pay attention to the following:
  - Avoid abrasion and pressure
  - If necessary support the leg in a slightly abductive position.
- The maximum continuous load on the leg support element is 30 kg.
- Movement must always be free of pain and irritation.
- The patient must be **fully conscious** during instruction and when using the splint.
- The doctor or therapist must decide on a case-to-case basis whether the device can be used with the patient.

⚠ PRECAUTION!
Before treatment begins, a test run involving several movement cycles should be carried out first without and then with the patient.

- The hand-held programming should be explained to the p and must be located **within patient's reach**, so that the can be interrupted if necess
- Make sure that the characte values of your **power suppl** spond to the voltage and fre data indicated on the ID pla
- Only connect the **ARTROMO** to correctly installed safty so
- **Repair** and **maintenance** w only be carried out by autho persons, as otherwise **all** wa services and liabilities shall
- Perform regular checks on a nents for possible damage c connections.
- Damaged or worn parts sho replaced immediately with o spare parts by an authorise cialist.
- Before cleaning and repair **d the device from the main s**
- When carrying out any work device, **never allow liquids** inside the housing or the ha programming unit.
- Only use the AC-AC adapte with the unit.

⚠ PRECAUTION
The ARTROMOT®-K4 may operated with the attache supply NTEV20.

To disconnect the device from unplug the AC-AC adapter fro socket.

usting the device

l out pages 2 and 3.
etter understanding of the
steps.

nnecting
e device

the **power adapter** (7) to a
ty socket (120 Volt, 60 Hertz)

he device with the **main**
15)

djusting the
mur length

vice at knee-angle position
likely to cause the patient

ing the upper leg

e black knurled knob (22),
ton and move thigh support
e desired length (figure 2).

ct alignment of the hip axis
nt (23) and anatomical hip
e patient pull button (1) and
ot point (23) to height of
er major of the patient.

ing the lower leg

he two knobs (8), move the
port horizontally and adjust
to the patients lower leg
gure 3).

ing of foot dorsi-/plantar

he two knobs (10) and adjust
plate at a comfortable angle

ing of foot rotation

he knurled knob (11) and
e foot plate into the required
position (figure 5).

4.3 Adjusting the patient kit

– Fix patient kit (18) for the lower leg and patient kit (20) for the upper leg by using the velcro tapes (figure 6 and figure 7).
– Control correct adjustment. Exercise only in painfree range of motion. Patient should be positioned with maximum comfort.

⚠ PRECAUTION!

The knee and hip axis of the ARTROMOT®-K4 should align with the patients knee and hip axis (figure 8).
After adjustments have been made, perform several test runs. When correctly adjusted, there should be no excursion of the knee and hip joint during motion.

4.4 Conversion

ARTROMOT®-K4 features a true anatomical knee and hip axis for maximum patient comfort.

ARTROMOT®-K4 has to be set up either for the right or left leg.

The device can be converted quickly. The procedure is easiest at an angle of approximatly 80–90 degrees (section 5.1.1).

– Hand-held programming unit (7) is in **STOP** mode.

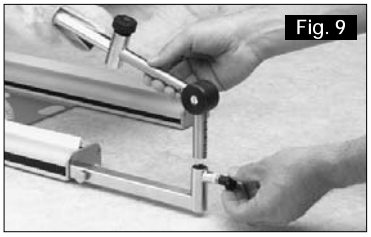


Fig. 9

– Pull button for height adjustment mechanism (1) and remove thigh support (21) (figure 9).

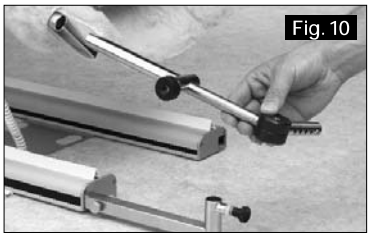
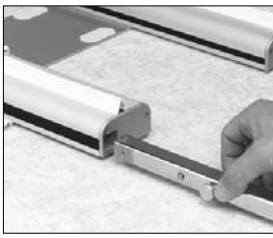


Fig. 10

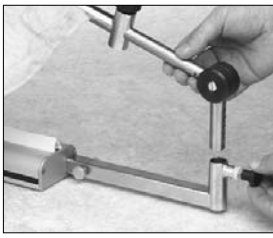
– Hold the thigh support. Release length adjustment mechanism (1/4 rotation) from the bayonet lock (figure 10).
Remove entire part and slide into the opposite side and fix in place with the bayonet lock.

⚠ PRECAUTION

For correct insert and loc
tion of the bayonet lock re
sticker on the device.



– Press buttons (3) simultaneo
pull square tube (2) associat
the heigth adjustment mech
from profile (figure 11). Slide
opposite profile until it "click
audibly.



– Slide the height adjustment
together again and allow hi
click home at the same heig
turning point of the hip (figu

ting the treatment values

ogramming the TROMOT®-K4

ng **treatment values** can
oy means of the **hand-held
ing unit.** (7)

ension
xion
xtension
exion

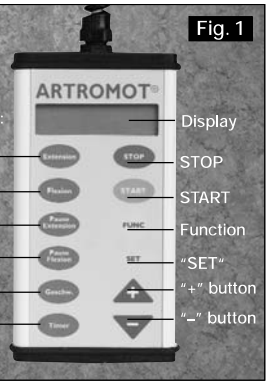


Fig. 1

rogramming the eatment values

NT:
le to program single or all
s. If only some parametres
ged, the other parameters
ed with current settings.

the **Extension and STOP**
he same time for one
or holding down the **STOP**
ive seconds enables you to
to **programming mode**.

2. You can now select the treatment values in succesion by pressing the parameter keys.
3. Change the value by pressing the **+/-** keys.
4. Continue programming (with 2 and 3) until all required values are entered.
5. Press the **STOP** key to save all previous values.
6. Press **START** button: programme values were checked automatically.
7. Press **START** button again to start the device in therapy mode.
8. Pressing the parameter buttons in stop mode the display shows the **current stored values**.

5.1.2 Information about treatment values

Setting the range of motion ROM

– Maximun **knee extension**: -10 degrees
– Maximum **knee flexion**: 125 degrees

⚠ PRECAUTION!
The programmed value and the actual angle measured at the patient´s knee may vary.

The criterion for correct adjustment is that it should be possible to move the extremity without pain or irritation.

Adjusting the pauses

– The pauses occur in the final position of extension of flexion and can be set seperately for extension and flexion.
– Possible values for pauses: 0–30 seconds.

Adjusting the force (reverse on load)

– Minimum setting for reverse on load: **25 kp**
– Maximum setting for reverse on load: **45 kp**

Settings are aproximate!

Tensile force is measured on the frame around the foot.

The input setting determines the maximum resistance needed to automatically reverse the direction of motion.

⚠ PRECAUTION!
The reverse circuit is purely a safty measure for cramps, spasms, locked joints, etc. The manufacturer accepts no liability if used improperly.

Speed
Minimum setting for speed: **1%**
Maximum setting for speed: **100%**

5.1.3 Programming the special functions

Special functions are:

– Center warm up
– Full speed & motion (double speed setting)
– Runtime (patient runtime)
– Device runtime

Programming the special functions:

1. Switch to programming mode (section 5.1.1)
2. Press **FUNC** key
3. Select special funtions using **+** or **-** key
4. Follow the instructions on the display
5. Quit and save with **STOP** button

Center warm up

Warm up allows the patient gr
attain full programmed range
The device starts in the middl
the two values set for extensi
flexion. With each movement
extent of movement is increas
2 degrees until the set value i
The device then moves betwe
values.

Full speed & motion

The full speed & motion functi
for service. The device runs at
the maximum programmable
facilitate a rapid device set up

**WARNING: Do not run the d
full speed & motion when pa
in the device!**

Run time

The individual run time for eac
ment. To reset press **SET** key
programming mode.

Device run time

The total device run time is co
from the first usage of the dev
+ button for 5 seconds until s
appears. Device run time can
deleted.

Save data

To save the programmed spec
tions, press the **STOP** key.

Press the **START** key: the devi
programmed values.

ntenance

nplug the device before

ROMOT®-K4 can be wiped
h desinfectant and therefore
with the required standards
e for medical equipment.

sing can be cleaned using
ly available disinfectants and
sehold detergents.

ce itself should only be wiped
th damp cloth.

RECAUTION!

**llow liquids to get inside
sing or hand-held pro-
ng unit.**

tics used are not resistant
al acids, formic acid, phenol,
xidising or strong organic
ganic acids with a pH value
an 4.

he device from intensive
t radiation (sunlight).

ng Conditions

g

e	-11° F to +140° F
midity	20 % to 85 %
e	700 hPa to 1060 hPa

al Conditions

g

e	+50° F to +104° F
midity	30 % to 75 %
e	700 hPa to 1060 hPa

7. Specifications

Electrical rating	115 V/230 V ~ 50/60 Hz 15 V/27 VA
Input current	0.3 Amps
Rated	1.33 A
Transformer	Safety transformer EN 60742
Protection class	II
Length	45.27 inches/115 cm
Width	15.5 inches/39.5 cm
Height	21.7 inches/55 cm
Length adjustment for lower leg	15.5 inches/39.5 cm - 22 inches/56 cm
Length adjustment for upper leg (approximate length)	12.5 inches/32 cm -19.7 inches/50 cm
Weigth	26 lb./13 kg
Materials used	Steel: 1.4301; 1.4305; 1.4310 Aluminium: AlMg3; AlCuMgPb F38, Brass Synthetic material: PA6.6; Polystyrol PVC; PE 1000; FR4 Electronic board; Polyurethane; rubber Support: synthetic fleece (Polyester)

Technical data subject to change

MPG:	Class 2a
Power supply	NTEV20 Safety Transformer In: 115/230 V ~ 50/60 HZ, 27 VA Out: 15 V ~ 1.33 A Manufacturer: Ulmer

8. Service

If you have any questions regarding product or service, please do not hesitate to contact us:

ORMED international
Please contact your local dealer or

Headquarters Germany
ORMED GmbH & Co. KG
Merzhauser Straße 112
D-79100 Freiburg, Germany

Tel. +49-(0)-761-4566-281
Fax +49-(0)-761-4566-55 281
e-mail: s.goerger@ormed.de

USA, St. Paul
Tel. 1-800-440-2784
Fax 1-651-415-7414
e-mail: r.suddendorf@ormedusa.com

Czech Republic, Prague
Tel. 02-84094650
Fax 02-84094660
e-mail: miroslav.fila@oemed.cz

Internet:
www.ormed.de
e-mail: s.goerger@ormed.de

www.ormedusa.com

Technical hotline:
Do you have any technical questions?
Do you need Technical service?

Tel. +49-180-5-1-ormed.de
+49-180-5-1-676 333
Fax +49-180-5-3-ormed.de
+49-180-5-3-676 333

⚠ PRECAUTION

**Carry out regular checks
intervals for possible dama
loose connections. Damag
worn parts should be repl
immediately with original
parts by an authorized sp**

To avoid transport damages, u
the original packing boxes. Th
boxes can be ordered from Or
Before carrying the device, alw
make sure the femur length ad
is locked.

Maintenance:
Not necessary

Guarantee:
2 years warranty on mechanic
electronical parts

Manufacturer:
ORMED GmbH & Co. KG
Merzhauser Straße 112
D-79100 Freiburg

Declaration of Conformity

According to the EC-Regulation for medical devices the
EC Medical Devices Directive (MDD) 93/42/EEC dated 14th June 1993,
appendix 2

The Manufacturer
ORMED GmbH & Co. KG
Merzhauser Straße 112
D-79100 Freiburg

herewith declares that the following units

Type **Knee & Hip**
Name **ARTROMOT®-K4**

meets all requirements of following EC-directives:

EN 60 601-1	**1990**	Electrical Medical Devices, Part 1, Basic Rules for Safety
EN 60 601-2	**1993**	Electrical Medical Devices, Part 1 and 2, additional norm: electromagnetic compatibility – requirements and testing

The adherence to the standard specifications entitles to marking of these devices with CE 0297.

CE
0297

Freiburg, January 20, 2002

Quality Control Manager

DIN EN 46 001 ORMED Nr. 018 829-01

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